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Human Experimentation

An Overview on Cold War Era Programs

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Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the use of humans in tests and experiments conducted for national security purposes by the Department of Defense (DOD) and other agencies between 1940 and 1974. As you requested, we collected information on the scope of these experiments and their possible impact. We obtained information on (1) the magnitude and scope of human subject experimentation, (2) the potential effects of the experiments on human subjects, (3) government efforts to assist those who may have been injured or suffered adverse health effects as a result of the tests or experiments, and (4) measures to ensure that informed consent is secured and that volunteers are protected in government-sponsored experiments.

BACKGROUND

As you requested, we focused our work on defense-affiliated programs that used human test subjects between 1940 and 1974. The programs included tests and experiments conducted or sponsored by the Departments of the Army, the Navy, and the Air Force; the Defense Nuclear Agency; the Central Intelligence Agency (CIA); the Department of Energy; and the Department of Health and Human Services. The tests and experiments involved radiological, chemical, and biological research and were conducted to support weapon development programs, identify methods to protect the health of military personnel against a variety of diseases and combat conditions, and analyze U.S. defense vulnerabilities.

RESULTS IN BRIEF

During World War II and the Cold War era, DOD and other national security agencies conducted or sponsored extensive radiological, chemical, and biological research programs. Precise information on the number of tests, experiments, and participants is not available, and the exact numbers may never be known. However, we have identified hundreds of radiological, chemical, and biological tests and experiments in which hundreds of thousands of people were used as test subjects. These tests and experiments often involved hazardous substances such as radiation, blister and nerve agents, biological agents, and lysergic acid diethylamide (LSD). In some cases, basic safeguards to protect people were either not in place or not followed. For example, some tests and experiments were conducted in secret; others involved the use of people without their knowledge or consent or their full knowledge of the risks involved.

The effects of the tests and experiments are often difficult to determine. Although some participants suffered immediate acute injuries, and some died, in other cases adverse health problems were not discovered until many years later--often 20 to 30 years or longer.

Federal programs provide benefits to former military and federal civilian employees who suffer from injuries or adverse health effects as a result of federal service. However, it has proven difficult for participants in government tests and experiments between 1940 and 1974 to pursue claims because little centralized information is available to prove participation or determine whether adverse health effects resulted from the testing. To address these problems, special efforts have been made by some involved agencies to help groups of test participants obtain the information necessary to pursue claims. For example, the Department of Veterans Affairs (VA) relaxed its requirement that participants link their health problems to those tests or experiments. Also, since 1978 DOD has had a program to identify and provide information to participants in atmospheric nuclear tests that were conducted between the 1940s and 1960s. More recently, in January 1994, the administration established an advisory committee to identify participants in other government-sponsored radiation research. We are reviewing the efforts of the committee at the request of the Senate Committee on Governmental Affairs.

In other areas, however, special efforts to make information available on test participants are not as far along. For example, DOD recently recognized a need to identify and assist participants in chemical tests conducted prior to 1968, but to date limited resources have been applied. We were told earlier this month that the VA continues to have difficulty processing claims because it cannot obtain necessary information from DOD. Some participants or their survivors have pursued benefits or compensation, outside existing federal programs, through specific congressional action or court awards.

Although military regulations in effect as early as 1953 generally required that volunteers be informed of the nature and foreseeable risks of the studies in which they participated, this did not always occur. Some participants have testified that they were not informed about the test risks. Government testing and experimentation with human subjects continues today because of its importance to national security agencies. For example, the Army's Medical Research Institute for Infectious Disease uses volunteers in its tests of new vaccines for malaria, hepatitis, and other exotic diseases. Since 1974, federal regulations have become more protective of research subjects and, in general, require (1) the formation of institutional review boards and procedures and (2) researchers to obtain informed consent from human subjects and ensure that their participation is voluntary and based on knowledge of the potential risks and benefits. We are in the process of reviewing the effectiveness of these measures. A National Institutes of Health official has stated that no mechanism exists to ensure implementation of the key federal policies in this area.

THE GOVERNMENT HAS SPONSORED EXTENSIVE TESTING, BUT PRECISE INFORMATION ON TESTS AND PARTICIPANTS IS NOT AVAILABLE

Precise information on the scope and magnitude of government tests and experiments involving human subjects is not available, and exact numbers may never be known. However, our review of available documentation and interviews with agency officials identified hundreds of tests and experiments in which hundreds of thousands of people were used as subjects. Some of these tests and experiments involved the intentional exposure of people to hazardous substances such as radiation, blister and nerve agents, biological agents, LSD, and phencyclidine (PCP). These tests and experiments were conducted to support weapon development programs, identify methods to protect the health of military personnel against a variety of diseases and combat conditions, and analyze U.S. defense vulnerabilities. Healthy adults, children, psychiatric patients, and prison inmates were used in these tests and experiments.

Documenting the precise number of tests and participants is difficult because government information is incomplete. Some records have been lost or destroyed, and existing documentation contains limited information and often does not identify names of participants. Moreover, these records are spread throughout the country at the National Archives, Federal Record Centers, other government offices, and the military commands or organizational units that created them. Some of the records measure thousands of linear feet, and the availability and quality of indexes to the records vary widely.

I will describe a few of the radiological, chemical, and biological research projects that illustrate the scope and magnitude of governmental experimentation.

Radiological Tests and Experiments

To date, over 200 radiation tests and experiments have been identified involving over 210,000 test participants. Although not involved in a test or experiment, another 199,000 people were exposed to radiation through work. This latter group is of concern because the effects of the exposure are the same as those incurred by test participants. The radiation tests are generally recognized as involving the largest number of test participants.

The largest known test program was the atmospheric nuclear test program conducted from 1945 to 1962. The purpose of this program was to develop weapons and to gain a better understanding of the tactical effect on troops. Over this 17-year period, approximately 210,000 DOD-affiliated personnel, including civilian employees of DOD contractors, scientists, technicians, maneuver and training troops, and support personnel, participated in 235 atmospheric nuclear tests. We reported on two of these tests, known as

Operation Crossroads, in 1985.¹ In some tests, participants were directly exposed to radiation. For example, in one test, five individuals were located directly beneath a high-altitude test. In other tests, 37 individuals were located in trenches from 2,000 to 2,600 yards from ground zero, and in others, approximately 26,000 individuals occupied trenches, bunkers, and armored vehicles from 2,500 to 5,500 yards from ground zero. According to DOD officials, as many as 150,000 of the 210,000 participants may have been exposed to fallout. In addition, 195,000 U.S. service members may have been exposed to radiation during the occupation of Hiroshima and Nagasaki, and over 4,000 other service members may have been exposed during cleanups at Bikini, Enewetak, and Johnston Atolls after nuclear tests were conducted. Some participants have alleged that they were not fully informed or did not understand the potential health risks of exposure to radiation.

In a series of experiments conducted between the 1940s and 1960s, the Atomic Energy Commission and the U.S. Public Health Service funded research of the potential medical effects on people from fallout after a nuclear attack or accident. In some of the experiments, university researchers exposed mentally disabled children to low doses of radiation. Years after the experiments were completed, a task force found that researchers failed to satisfactorily inform the subjects' families about the nature and risk of the experiments in order for them to make an informed decision when they gave their consent. The president of one of the universities involved in the experiments later apologized for the use of children and the failure to provide full information about the nature and risk. We are not aware of what, if any, further action was taken in this case.

Chemical Tests and Experiments

During World War II and the Cold War era, the Army and the Navy conducted two major chemical research experiments in which thousands of service members were used as test subjects. An unknown number of other chemical tests and experiments were conducted under contracts with universities, hospitals, and medical research facilities. In some of the tests and experiments, healthy adults, psychiatric patients, and prison inmates were used without their knowledge or consent or their full knowledge of the risks involved.

During World War II, the Army conducted tests of protective clothing and equipment in which thousands of people were exposed to mustard gas and lewisite agents. In addition, the Army developed and tested offensive chemical weapons and evaluated the effectiveness and persistency of mustard agents in different

¹Operation Crossroads: Personnel Radiation Exposure Estimates Should Be Improved (GAO/RCED-86-15, Nov. 8, 1985).

environments. In February 1993, we reported that the Army's records of its mustard test activities were not kept in a manner that readily identifies the participants.² However, the available records show that 1,002 soldiers were commended for their participation in tests in which they subjected themselves to pain, discomfort, and possible permanent injury for the advancement of research in protection of the armed services.

Similar to the Army's tests, the Navy conducted tests of clothing and equipment that exposed thousands to the effects of mustard gas and lewisite agents. These experiments involved (1) gas chamber tests, in which service members were completely exposed to mustard and lewisite agents while wearing protective clothing, and (2) skin tests, in which amounts of mustard agent and antivesicant ointments were applied to service members' forearms. The Navy has a list of the names of approximately 3,200 sailors who participated in mustard and lewisite agent tests performed by the Naval Research Laboratory. Additionally, Navy officials told us that between 15,000 and 60,000 Navy recruits had participated in skin tests conducted by a contractor but that the Navy had no record of the recruits' names.

From 1952 to 1975, the Army conducted a classified medical research program to develop incapacitating agents. The program involved testing nerve agents, nerve agent antidotes, psychochemicals, and irritants. The chemicals were given to volunteer service members at the Edgewood Arsenal, Maryland, and four other locations. Army documents identify a total of 7,120 Army and Air Force personnel who participated in these tests, about half of whom were exposed to chemicals. The Army's Medical Research and Development Command in Fort Detrick, Maryland, has the names and service numbers of all test participants and a list of the chemicals to which the service members were exposed. Some service members have testified before congressional committees that they were not fully informed of the risks involved.

During the same period, the Army Chemical Corps contracted with various universities, state hospitals, and medical foundations to research the disruptive influences that psychochemical agents could have on combat troops. The Air Force also conducted experiments on the effects of LSD through contracts at five universities. According to Air Force officials and records, approximately 100 people received LSD in these experiments. No effort has been made by the Air Force to determine if the participants' names are available in the universities' records.

²Veterans Disability: Information From Military May Help VA Assess Claims Related to Secret Tests (GAO/NSIAD-93-89, Feb. 18, 1993).

According to a CIA official, from 1953 to about 1964, the CIA conducted a series of experiments called MKULTRA to test vulnerabilities to behavior modification drugs. As a part of these experiments, LSD and other psychochemical drugs were administered to an undetermined number of people without their knowledge or consent. According to the official, the names of those involved in the tests are not available because names were not recorded or the records were subsequently destroyed. However, some tests were done under contract, and no effort has been made by the CIA to determine if names are available in contractors' records.

Biological Tests and Experiments

The Army conducted a series of biological warfare experiments and tests between 1949 and 1974. The purpose of these tests was to determine U.S. vulnerabilities to biological warfare. For example, between 1949 and 1969, the Army conducted several hundred biological warfare tests in which unaware populations were sprayed with bacterial tracers or simulants that the Army thought were harmless at that time. Some of the tests involved spraying large areas, such as the cities of St. Louis and San Francisco, and others involved spraying more focused areas, such as the New York City subway system and Washington National Airport.

In another Army experiment conducted between 1959 and 1974, approximately 2,200 volunteers were exposed to biological pathogens, such as Venezuelan Equine Encephalitis and Tularemia, as part of research to develop vaccines and antidotes. A list of all studies and medical records of all volunteers are located at the Army's Medical Research Institute of Infectious Diseases in Fort Detrick, Maryland. It appears that the participants were adequately informed.

EFFECTS OF EXPERIMENTS ARE OFTEN DIFFICULT TO DETERMINE

The effects of government tests on participants' health have been difficult to determine. At the time of the tests, some people were clearly harmed. However, in other cases, possible adverse health effects related to the substances used were unknown or did not become apparent until years later.

Available records show that people suffered immediate acute injuries in some tests and that people died in at least two tests. For example, available records show that some participants in the Army's and the Navy's mustard and lewisite tests suffered burns and required hospitalization. Also, in a highly publicized case, an Army employee died in 1953, a short time after participating in a CIA experiment using LSD.

However, for some test participants, the test effects were not readily apparent. In these cases, claimed adverse health problems

did not appear until many years later. For example, in our February 1993 report on the Army's chemical testing program, we noted that the first health problems for most of the veterans who sought assistance appeared many years after their military service and at a time when these same ailments typically show up in their general age population. Further, only a few of the veterans alleged that their health problems were long term in nature, dating back to their active military duty. We reported that 97 of 145 veterans seeking assistance could not prove that their health problems were caused by participation in a test or experiment.

Research studies have also shown that exposure to some of the substances used in the tests may create health problems that often will not appear for many years. For example, the National Academy of Sciences concluded in 1993 that exposure to mustard agents could cause many serious diseases that would not immediately appear, such as leukemia, emphysema, respiratory and skin cancers, and eye diseases, and that lewisite agents could cause some of these same diseases.

INFORMATION AVAILABLE TO ASSIST TEST PARTICIPANTS VARIES

Two federal agencies, the VA and the Department of Labor, have programs to provide medical care and disability benefits to former military and federal civilian personnel who have experienced health problems as a result of their participation in government tests or experiments. However, because there is not complete information on those who participated and the precise adverse health effects of their participation, it has often proven difficult for former test participants to pursue claims. To address these problems, special efforts have been made by some involved agencies to help groups of test participants obtain the information necessary to pursue claims. Other involved agencies, however, are not providing the information test participants need. Apart from the information issue, some participants or their survivors have sought compensation or benefits directly through civil or specific congressional actions.

The largest special information assistance effort is the Nuclear Test Personnel Review program, established by DOD in 1978. This program, administered by the Defense Nuclear Agency, has assisted veterans by compiling data on atmospheric nuclear tests, including the names of participants, the locations of the tests, and the amount of radiation administered during the tests.³ This program also involves an extensive outreach program that provides documents

³In October 1979, DOD expanded the program to include U.S. service personnel who had participated in the postwar occupation of Hiroshima and Nagasaki.

about the tests and informs participants of the availability of VA-provided health care and disability benefits.

Other special actions have also been taken to help some veterans pursue health claims related to their participation in testing. In 1988, the Congress directed the VA to relax its claims adjudication procedures for veterans exposed to radiation resulting from atmospheric nuclear detonations. For veterans with certain ailments that may be attributable to radiation exposure, the VA presumes that the ailments are service connected. In 1992, the VA amended its regulations so that veterans of mustard testing receive similar treatment if they develop certain diseases. In 1994, the regulations were further amended to include lewisite.

Earlier this year, the administration initiated a large effort to gather data on people who participated in experiments involving intentional exposure to ionizing radiation and intentional environmental releases of radiation. The Presidential Advisory Committee on Human Radiation Experiments, established in January 1994, is conducting this review. We are currently reviewing the efforts of the advisory committee at the request of the Chairman, Senate Committee on Governmental Affairs.

Let me describe some areas in which information is still needed.

Our February 1993 report stated that the military services lacked complete information on their chemical test activities and recommended that DOD aggregate the information and provide a point of contact within each service to assist veterans in obtaining information about their test experiences. DOD, in turn, established the Chemical Weapons Exposure Task Force to identify chemical test information and tasked the Secretaries of the Army, the Navy, and the Air Force to provide information related to the tests to the task force. However, to date (1) the task force employs only one full-time investigator, (2) the Army and the Navy have not designated points of contact to lead this effort, and (3) the services have not conducted a complete and thorough search of their records. Without this assistance, the VA continues to have difficulty assisting former test participants. For example, we were told in September 1994 that VA claims adjudicators misdirect over 100 test information requests monthly because they do not know which agency should receive them.

A similar situation exists with some other groups. For example, some agencies have made little effort to assist test participants by identifying test locations and participants in experiments conducted by contractors. The CIA, in fact, has not released the names of 15 of the approximately 80 organizations that conducted experiments under the previously discussed MKULTRA program because the organizations do not want to be identified.

Conclusive information on the effects of some biological simulants used in the Army's testing is not available. Recently, the Army had the Centers for Disease Control review its risk assessments for one simulant used in some of its biological warfare tests. The Center determined that adverse health effects from the levels of exposure to the simulant, zinc cadmium sulfide, at those sites were very unlikely. However, the Fiscal Year 1995 Defense Appropriation Bill provides \$1 million to further study possible adverse health effects of exposure to this simulant.

Finally, in the case of civilian government employees, whose claims for compensation are processed through the Department of Labor, we were told that the rules have not been relaxed in the same way as they have been at the VA. In some cases, civilian employees participated in the same testing as military service members.

In selected cases, test and experiment participants have received compensation as a result of a civil action or specific congressional action. For example, in 1976 the President signed legislation providing \$750,000 to the family of an LSD test participant who died in 1953 shortly after being administered LSD.⁴ Also, the Justice Department settled a suit brought by another group of LSD test participants for \$750,000. Another example of a specific congressional action is the establishment of a \$100 million fund to cover claims from individuals who lived downwind from locations where above-ground nuclear tests were conducted.⁵ Similarly, another act authorized \$184 million for Marshall Islands citizens who may have been exposed during nuclear testing.⁶ These funds are distributed to individual islands and disbursed by the local governments.

GOVERNMENT EFFORTS TO STRENGTHEN THE PROTECTION OF HUMAN PARTICIPANTS

Although guidance for protecting human subjects has existed since the post-World War II Nuremberg trials, the principles were not always followed by U.S. government researchers. It was not until the 1970s that the Congress and some agencies became actively involved in examining human research ethics and establishing laws and regulations that became progressively more protective of human subjects. In 1974, the Department of Health, Education, and Welfare issued a regulation strengthening the Department's informed consent procedures and institutional review requirements. In 1991, the Department of Health and Human Services issued a revised, uniform regulation for the protection of human subjects that was

⁴Private Law 94-126.

⁵The Radiation Exposure Compensation Act (P.L. 101-426).

⁶The Compact of Free Association Act of 1985 (P.L. 99-239).

adopted by 16 federal agencies, including DOD, CIA, and other national security agencies.

The 1947 Nuremberg Code of Ethics established the fundamental principles for scientists and physicians involved in using people as subjects in experiments and tests. In the Nuremberg Code, the respect for the human rights of patients, including their voluntary consent and their safety from undue physical or psychological harm, was of paramount consideration. A 1953 memorandum from the Secretary of Defense to the secretaries of the military services directed them, in essence, to adopt the Nuremberg Code as a guide for human experimentation. However, according to defense officials, some of the rules, including those related to the quality of informed consent and the capability of the subjects to withdraw without prejudice, were not followed in the 1950s and 1960s.

In 1964, the Declaration of Helsinki emphasized that clinical research using people as subjects should be (1) based on laboratory and animal experiments or on scientifically established facts, (2) conducted by scientifically qualified medical persons, (3) preceded by a careful assessment of the inherent risks versus benefits, and (4) generally done with disclosure of the risks to the subjects and with the subjects' free consent. In November 1966, the American Medical Association adopted the ethical principles of the Helsinki Declaration to guide physicians engaged in clinical research and investigations of new drugs and procedures.

The federal regulation issued in 1974 by the Department of Health, Education, and Welfare covers the protection of humans in experiments and tests and requires all institutions carrying out research funded by the department to have an Institutional Review Board. The boards are to review the risks and benefits of the proposed research, the specific procedures to be followed, and the process of informing the human subject and obtaining consent. The regulation also requires institutions to describe the test procedures and the foreseeable risks or discomforts and explain that subjects can refuse to participate at any time. In general, federal departments incorporated parts or all of this regulation in their policies on human experimentation.

The Department of Health and Human Services' 1991 regulation replaced previous federal policies and regulations and clarified requirements for researchers to obtain informed consent from human subjects and ensure that their participation is voluntary and based on knowledge of the potential risks and benefits. The regulation was subsequently adopted by 16 other federal agencies.

This concludes my prepared statement, Mr. Chairman. I will be happy to answer any questions.

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